

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Involving patients and clinicians in a pilot randomised clinical trial of spinal manual therapy versus nerve root injection for lumbar radiculopathy: protocol of a patient and public involvement project
AUTHORS	Ryf, Corina; Hofstetter, Léonie; Clack, Lauren; Puhan, Milo; Hincapié, Cesar

VERSION 1 – REVIEW

REVIEWER	Kory Zimney University of South Dakota, Physical Therapy
REVIEW RETURNED	28-Jan-2022

GENERAL COMMENTS	<p>Main impression and General Recommendations: This is a study protocol for patient and public involvement (PPI) project embedded withing a larger trial. I commend the authors for taking the important step of getting PPI as part of their larger trial. The study protocol explains the primary steps involved in the qualitative data collection process for this PPI project.</p> <p>Major Comments: Pg 8, Ln 150. Why are you predetermining the potential number of participants to provide feedback? (patients n=2-4) Why not just take the stance of data saturation as your endpoint to stop feedback with the a priori prediction being the (n) numbers listed? Pg 10, Ln 219 Here it states the interviewer will be taking notes during the think aloud method, but in the previous section it states that the assistants will be taking notes. Please clarify. Also please provide some statements on how discrepancies of the note taking by the different assistants might be handled if it were to occur.</p> <p>Minor Comments: Pg 8, Ln 158. You may want to gather a few patients from outside the system. They may provide a different perspective from those that have gone through the system where the research will take place. Good to see you are getting PCP involvement from the surrounding region to provide a wide breadth of insights. Pg 10, Ln 225 Why the differences in use of German and English interview languages with patients and PCP's? May want to include in participant recruitment of patients and PCPs their language ability. May want a statement regarding if participants in the PPI project are receiving any monetary or other compensation for their involvement.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comments (Dr. Kory Zimney):

Major comments

1. Pg 8, Ln 150. Why are you predetermining the potential number of participants to provide feedback? (patients n=2-4) Why not just take the stance of data saturation as your endpoint to stop feedback with the a priori prediction being the (n) numbers listed?

Response: Thank you for this input. For the think aloud method we aim to recruit participants one after the other until we gain no more additional information. We changed (Pg 6, Lines 152- 155):

To gain feedback on language and content of patient trial documents, additional patients will be recruited one after another to participate in a think-aloud process until no new feedback is generated (a priori estimation, n = 2 to 4).

2. Pg 10, Ln 219 Here it states the interviewer will be taking notes during the think aloud method, but in the previous section it states that the assistants will be taking notes. Please clarify. Also please provide some statements on how discrepancies of the note taking by the different assistants might be handled if it were to occur.

Response: Thank you for raising this point. We corrected (Pg 8, line 225):

An assistant will take notes to contribute to the digitally recorded material.

And we added (Pg 8, lines 219):

The assistants will record the interview and take comprehensive notes, with any discrepancies in notes resolved by consensus.

Minor comments

1. Pg 8, Ln 158. You may want to gather a few patients from outside the system. They may provide a different perspective from those that have gone through the system where the research will take place. Good to see you are getting PCP involvement from the surrounding region to provide a wide breadth of insights.

Response: We are open to recruit not only patients from the clinical setting at the Balgrist University Hospital but also from internal and external collaborating clinicians, which would help to provide a broader perspective (Pg 6, line 161-163):

Patient advisors will be current or former patients of the chiropractic medicine polyclinic at Balgrist University Hospital in Zurich Switzerland, or from other internal or external collaborating clinicians.

2. Pg 10, Ln 225 Why the differences in use of German and English interview languages with

patients and PCP's? May want to include in participant recruitment of patients and PCPs their language ability.

Response: Whereas patients in the area around Zurich speak mostly German, almost all clinicians in Switzerland are fluent in the English language. We specified (Pg 8, lines 232 – 235):

Communication with patient advisors will be in German (interviews, member-checking) as this is the primary language in the region and the data collected will be subsequently translated to English. As almost all clinicians in Switzerland are proficient in English (global academic language), clinician advisors will be interviewed in English.

3. May want a statement regarding if participants in the PPI project are receiving any monetary or other compensation for their involvement.

Response: We added the following information (Pg 6, lines 176 – 179):

Patient and clinician advisors will not be incentivized to participate through any offer of monetary or other compensation for their involvement, but a small token of appreciation (gift card of small value) will be provided in thanks for their involvement after completion of the PPI activities.

VERSION 2 – REVIEW

REVIEWER	Kory Zimney University of South Dakota, Physical Therapy
REVIEW RETURNED	25-Mar-2022
GENERAL COMMENTS	All of my original comments were adequately addressed. Thank you for the opportunity to review this revision.